(26)

No. 03-1454

IN THE

Supreme Court of the United States

JOHN ASHCROFT, ET AL.,
Petitioners,

v.

ANGEL MCCLARY RAICH, ET AL.,
Respondents.

On Writ of Certiorari to the United States Court of Appeals for the Ninth Circuit

AMICUS CURIAE BRIEF OF THE MARIJUANA POLICY PROJECT AND RICK DOBLIN, Ph.D. IN SUPPORT OF THE RESPONDENTS

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IDENTITY AND INTEREST OF *AMICI CURIAE*

The Marijuana Policy Project (MPP) and Rick Doblin, Ph.D. respectfully submit this brief as *amici curiae* in this case. Letters from Petitioner and Respondents granting consent to the filing of this brief have been filed with this Court.[1]

[1] Pursuant to S.Ct. Rule 37.6 counsel certifies that no counsel for a party authored any part of this brief. No person or entity other than *amici* made a monetary contribution to the preparation or submission of the brief.

MPP (www.mpp.org) is a non-profit, public interest advocacy organization representing more than 1,000 seriously ill people throughout the nation who are struggling to obtain legal access to medical cannabis. Since 1995, MPP and several of its seriously ill clients have met with officials from the FDA, the National Institutes of Health, and the National Institute on Drug Abuse (NIDA). MPP representatives have also testified before the National Academy of Sciences' Institute of Medicine (IOM) and the American Medical Association House of Delegates. MPP's clientele, like thousands of other patients nationwide, must choose between suffering or following their doctors' orders to use medical cannabis—even though the latter may result in a federal prison sentence. Consequently, MPP is exhausting all options to provide a legal avenue through which its clients may obtain and use medical cannabis. Rob Kampia is the co-founder and executive director of MPP.

Rick Doblin has a Ph.D. in Public Policy from the Kennedy School of Government, Harvard University. He is the founder and current director of the Multidisciplinary Association for Psychedelic Studies (MAPS, www.maps.org), a non-profit membership-based research and educational organization and pharmaceutical company that works to develop cannabis and other Schedule I drugs into Food and Drug Administration (FDA)-approved prescription medicines. MAPS helped support the successful five-year struggle of Dr. Donald Abrams, University of California-San Francisco, to obtain permission to conduct research into the effects of smoked cannabis in HIV+ subjects. Dr. Abrams's study, which enrolled the first subject in 1998, was the first FDA-approved study of the medical use of smoked cannabis in a patient population in twelve years. MAPS holds the only Orphan Drug designation granted by the FDA for any medical use of the cannabis plant itself, specifically in the treatment of AIDS patients suffering from HIV-related wasting syndrome. MAPS thus has a commercial interest in developing the

cannabis plant into an FDA-approved prescription medicine for AIDS-wasting, and potentially for other clinical indications as well.

A prerequisite for any practical, privately-funded, cannabis drug development program is access to independently selected strains of cannabis and control over issues of cost and timely availability. For the last several years, MAPS has offered a grant to Prof. Lyle Craker, University of Massachusetts at Amherst (UMass Amherst), Director, Medicinal Plant Program, Department of Plant and Soil Sciences, to establish a small medical cannabis production facility to grow high-potency cannabis for use in FDA and DEA-approved protocols. Prof. Craker first applied for a license to the Drug Enforcement Administration (DEA) in June 2001, and is still waiting for a decision. MAPS has also sponsored laboratory research into the use of a vaporizer device, a non-smoking delivery system which heats the marijuana plant but doesn't burn it, releasing cannabinoids without toxic byproducts of combustion. The development of such devices was recommended by the Office of National Drug Control Policy-funded Institute of Medicine report. As of October 12, 2004, an application submitted on June 24, 2003 to NIDA from Chemic Laboratories, working under contract to MAPS, to purchase 10 grams of cannabis for further vaporizer research, has languished for over fifteen months without a response. An application from Chemic to the DEA, also submitted on June 24, 2003, to import 10 grams from the Dutch Office of Medicinal Cannabis has also not received a response. As a result of the lack of response, on July 21, 2004, MAPS filed a lawsuit against DEA and a separate one against HHS/NIH/NIDA, arguing unreasonable delay under the Administrative Procedures Act and claiming federal obstruction of its privately-funded cannabis drug development research effort.

SUMMARY OF THE ARGUMENT

The federal government, specifically NIDA of the U.S. Department of Health and Human Services (HHS), retains a restrictive and unnecessary monopoly over the only supply of cannabis that is currently allowed to be used in FDA-approved clinical trials. DEA sustains this monopoly by refusing to license any privately-funded production facilities. HHS and NIDA have exercised this monopoly over cannabis so as to impede the normal drug development process contemplated by Congress. Most recently, NIDA and HHS have unreasonably imposed an additional layer of regulatory review over privately funded clinical research with cannabis. No other Schedule I drug has to endure such an obstacle course.

In the instant case, this Court is being asked to decide whether patients have a constitutional right to use cannabis despite the Controlled Substances Act, 21 U.S.C. §801 *et seq*. Amici urge the Court to keep in mind that the FDA drug development process, the most direct and appropriate method for authorizing the provision of cannabis to patients with a legitimate, medical need for the drug, has been politically hobbled. The lack of FDA-approval of cannabis as a prescription medicine is due, in large part, to the systematic hindrance of scientific research by governmental agencies over the last several decades. The Court should not rule against patients' constitutional rights to use cannabis based on the illusion of a well-functioning FDA-approval process. Executive branch obstructionism has made it necessary for severely ill patients to assert their constitutional rights in order to obtain relief from life-threatening and disabling conditions.

THE ARGUMENT

I. ASSERTING PATIENTS' CONSTITUTIONAL RIGHTS TO USE CANNABIS IS THE ONLY REASONABLE ALTERNATIVE GIVEN THE GOVERNMENT'S OBSTRUCTION OF FDA-APPROVED RESEARCH INTO THE POTENTIAL THERAPEUTIC USES OF CANNABIS

A. An Agency of the Federal Government Has a Monopoly on the Legal Supply of Cannabis for Use in FDA-Approved Research.

The Single Convention on Narcotic Drugs, to which the United States is a Party, regulates the manufacture of cannabis within the boundaries of the signatory nations.[2] Under Article 23 2(e) of the convention, a private, non-governmental organization can obtain permission from a Party to grow cannabis for licensed medical uses without the Party coming into violation of any of the provisions of the Convention. The non-governmental producer would not need to sell its output to the government and could distribute its stocks for medical purposes to the extent that it was licensed to do so. In the United States, NIDA has a monopoly on the supply of FDA-approved research-grade cannabis for use in human subjects.[3] Sponsors of research into the medical uses of cannabis cannot at present manufacture their own supplies of research material but must instead petition to purchase federal supplies at cost from NIDA.[4]

[2] Single Convention on Narcotic Drugs, March 30, 1961, 18 U.S.T. 1407 (entered into force in the United States on June 24, 1967), available at http://www.incb.org/e/ind_ar.htm.

[3] NIDA contracts with the University of Mississippi to grow cannabis for research purposes, under the direction of Professor Mahmoud El-Sohly. The University of Mississippi facility holds the only license issued by the DEA for the production of cannabis for human consumption.

[4] FDA has not permitted researchers to use seized cannabis for research purposes due to uncertain purity and the inability to conduct subsequent studies with a standardized and replicable product.

The NIDA monopoly has been an impediment to objective and accurate scientific research. NIDA's institutional mission is to sponsor research into the understanding and treatment of the harmful consequences of the use of illegal drugs and to conduct educational activities to reduce the demand for and use of these illegal drugs.[5] NIDA's mission makes it a singularly inappropriate agency to be responsible for expeditiously stewarding scientific research into potential beneficial medical uses of cannabis. Furthermore, as with many monopolies, the quality of its product is low,[6] and access is restricted.

Accordingly, members of the medical community have opposed NIDA's policies relating to the supply of cannabis for scientific research into its potential medical uses. In December 1997, the AMA House of Delegates resolved "[t]hat the AMA urge the National Institutes of Health (NIH) to implement administrative procedures to facilitate grant applications and the conduct of well-designed clinical research into the medical utility of marijuana."[7] The House of Delegates stressed that "marijuana of various and consistent strengths and/or placebo" should be supplied by NIDA to

[5] See website of the National Institute on Drug Abuse, http://www.drugabuse.gov/about/AboutNIDA.html.

[6] MAPS and California NORML conducted a scientific study of the potency of cannabis used by patients across the country. This potency was then compared to the average potency of the cannabis that NIDA provides to the seven remaining patients who are part of the Compassionate Investigational New Drug program. Patients preferred cannabis that was roughly three to four times more potent than what NIDA supplies. The primary advantage of more potent cannabis is that it enables patients to inhale less smoke and particulate matter per unit of therapeutic cannabinoids. Dale Gieringer, Ph.D. *Medical Cannabis Potency Testing Project*, 9 MAPS, Autumn 1999, available at http://www.maps.org/newsletters/v09n3/09320gie.html, at 20-22.

[7] Council on Scientific Affairs, AMA House of Delegates, Report 10 - Medical Marijuana, Recommendations (1997).

clinical researchers who have received FDA approval, "regardless of whether or not the NIH is the primary source of grant support.[8] However, NIDA has resisted supplying research cannabis to MAPS's privately funded studies, which has limited research and hobbled the process by which cannabis could become available as a prescription medicine.

In contrast, in England, which is also a Party to the Single Convention, the Home Office granted a license to GW Pharmaceuticals, a non-governmental for-profit corporation, to grow cannabis for the manufacture of cannabis extracts to be used in clinical trials.[9] Since that time, GW has completed several Phase III clinical trials with its marijuana extract and has entered into marketing agreements for this product. [10] The International Narcotics Control Board (INCB), which monitors member nations' compliance with international drug control treaties, has never objected to the British Home Office licensing of GW Pharmaceuticals to grow cannabis, either in any of its annual reports or any other publications, letters, or meetings.

B. FDA-Approved Research into the Therapeutic Uses of Cannabis Has Been Blocked by NIDA and DEA.

1. *Government opposition has deterred and limited objective scientific studies into the beneficial uses of cannabis.*

Ideally, after a physician has determined that a patient has a medical need for the use of the cannabis plant, the patient should be able to obtain it in the form of an FDA-approved

[8] *Id.*

[9] *See* website of GW Pharmaceutical company, www.gwpharm.com/faqs.asp#faqs1_6.

[10] *See* website of GW Pharmaceutical company, http://www.gwpharm.com/news_press_releases.asp.

prescription medicine that is standardized for purity and potency. For this outcome to be realized, a pharmaceutical company must first submit to FDA sufficient scientific data proving safety and efficacy in a specific patient population, with the data gathered in controlled clinical trials conducted with prior approval of the FDA and DEA. [11]

Despite persisting interest in the medical research community into the exploration of the medical uses of cannabis, not one single patient in the United States received cannabis in the context of an FDA-approved study during the 12-year period between 1986—when the last of the state studies into the use of smoked cannabis in controlling nausea and vomiting in cancer chemotherapy patients concluded[12]—and 1998, when Dr. Donald Abrams at the University of California-San Francisco administered smoked cannabis to the first HIV+ subject in his groundbreaking AIDS-wasting study.[13] Dr. Abrams had to struggle for five years to obtain permission to conduct his study, three years of which were involved with a fruitless effort to obtain cannabis from NIDA for his study after his initial protocol had been approved by FDA.[14] In May 1995, MAPS even tried to enter into a contract with Prof. Mahmoud El-Sohly, Director of NIDA's University of Mississippi cannabis farm, to produce cannabis for Dr. Abrams's study. Prof. El-Sohly was initially interested in exploring this idea but eventually declined, presumably so

[11] *See* Food and Drug Administration, Guidance for Industry: Providing Clinical Evidence of Effectiveness for Human Drug and Biological Products (1998), *available at* http://www.fda.gov/cder/guidance/1397fnl.pdf

[12] R. Randall, 2 Marijuana, Medicine & the Law, 250. The States were California, New York, New Mexico, Tennessee, Georgia, Michigan and Washington.

[13] Donald Abrams, *Medical Cannabis: Tribulations and Trials*. 30 J. of Psychoactive Drugs, Apr.-Jun. 1998, at 163-69.

[14] *Id.*

as to not upset NIDA, his primary funder. Following and perhaps precipitated by California's 1996 passage of Proposition 215, which provided legal access to cannabis for patients whose physicians recommended it to them, NIDA indicated to Dr. Abrams that it might be willing to work out some arrangement whereby his long dormant FDA-approved study could go forward. In order to proceed at all, NIDA demanded that Dr. Abrams transform his FDA-approved protocol, designed to assess safety and efficacy in AIDS-wasting patients, into a safety study primarily evaluating the risks of cannabis in AIDS patients who did not suffer from AIDS-wasting syndrome.[15] Dr. Abrams and MAPS decided to accept NIDA's offer in order to start the research effort.

2. *Federal agencies have blocked the supply of cannabis for clinical research through unreasonable delay of applications.*

DEA and NIDA have further crippled research of medicinal cannabis by stalling the applications of parties interested in providing cannabis to researchers conducting FDA-approved studies. These agencies have resisted attempts to manufacture research cannabis as well as attempts to import it. Delays in the processing of applications have left parties unable to proceed with research or to appeal an adverse decision and have therefore obstructed the FDA approval process that Congress intended to make safe and effective medicines available to the public.

In June 2001, Prof. Lyle Craker, UMass Amherst, Director, Medicinal Plant Program, Department of Plant and Soil Sciences, with sponsorship from MAPS, applied to DEA for a

[15] Letter from Dr. Alan I. Leshner, Director of NIDA to Dr. Donald Abrams (Apr. 19, 1995), *available at* http://www.maps.org/mmj/leshner.html; Letter from Dr. Donald Abrams to Dr. Alan I. Leshner, Director of NIDA (April 28, 1995), *available at* http://www.maps.org/mmj/abrams.html.

license to establish a small medical cannabis production facility to supply high-quality research material to researchers with FDA and DEA-approved protocols.[16] More than three years later, Prof. Craker has still not received a decision on his application and remains stuck in a bureaucratic morass that prevents him from enabling research to study the potential beneficial uses of cannabis.

A chronology of the path of Prof. Craker's application illustrates the obstructionism that characterizes the inadequate process for furthering medical cannabis research. In December 2001, Prof. Craker was told by DEA that his application was lost. In February 2002, DEA refused to accept a photocopy of the application since it lacked an original signature, DEA having claimed to have lost the original document. On June 6, 2002, five Massachusetts Congressional Representatives sent a letter to DEA Administrator Asa Hutchinson expressing support for the licensing of a privately-funded cannabis production facility.[17] On July 1, 2002, DEA Administrator Asa Hutchinson replied to the Congressmen, stating DEA opposition to private production facilities based on supposed restrictions imposed by US international treaty obligations.[18] Later in July 2002, DEA returned the original application to Prof. Craker, unprocessed, with no individual's name on the return address or cover note, and with a DEA date-stamp showing that it had been received by DEA in June 2001. In August 2002, Prof. Craker re-

[16] Timelines and supporting documents available at www.maps.org/mmjfacility.html.

[17] Letter from United States Congressmen Michael E. Capriano, William D. Delahunt, Barney Frank, James P. McGovern, and John W. Oliver to Asa Hutchinson, DEA Administrator (June 6, 2002), *available at* http://www.maps.org/mmj/mmjfacility.html.

[18] Letter from Asa Hutchinson, DEA Administrator, to Congressman Barney Frank (Jul. 1, 2002), *available at* http://www.maps.org/mmj/mmjfacility.html.

submitted his original application, along with an analysis of U.S. international treaty obligations demonstrating that private production facilities were not prohibited.[19] On December 16, 2002, two DEA agents traveled to UMass Amherst to meet with Prof. Craker and senior UMass Amherst officials. The DEA agents encouraged them to withdraw the application, which they declined to do.

It was not until March 4, 2003, more than 20 months after his original application was filed, that Prof. Craker received his first direct written reply from DEA, from Mr. Frank Sapienza, Chief, Drug and Chemical Evaluation Section.[20] Mr. Sapienza reported that DEA considered NIDA's supply to be adequate for the research community and that DEA was "not persuaded" by Dr. Russo's December 30, 2002 letter [21] complaining about the low quality of NIDA material and discussing NIDA's refusal to supply him with cannabis for his FDA-approved protocol. Mr. Sapienza told Prof. Craker that in order for DEA "to further consider [his] application," he would need to submit "credible evidence" supporting his assertion that researchers were not adequately served by NIDA cannabis.[22] Prof. Craker responded to this request on June 2, 2003. In October, 2003, DEA again heard from elected representatives in support of Prof. Craker's application when Massachusetts Senators Edward Kennedy and

[19] The legal analysis was prepared pro-bono by lawyers with the D.C. law firm of Covington & Burling, in association with the American Civil Liberties Union Drug Policy Litigation Project. Their analysis is available at http://www.maps.org/mmj/mmjfacility.html.

[20] Letter from Frank Sapienza, Chief, DEA Drug and Chemical Evaluation Section, to Prof. Lyle Craker (Mar. 4, 2003), *available at* http://www.maps.org/mmj/mmjfacility.html.

[21] Letter from Dr. Ethan Russo to Mr. Simes, Drug Enforcement Administration (Dec. 30, 2002), *available at* http://www.maps.org/mmj/mmjfacility.html.

[22] *Id.*

John Kerry sent a letter stating their opposition to the NIDA monopoly on research cannabis. The Senators noted that lack of adequate competition "jeopardizes important research into the therapeutic effects of marijuana for patients undergoing chemotherapy or suffering from AIDS, glaucoma, or other diseases."[23]

In addition to the delay tactics cited above, DEA has failed to follow the procedures mandated by law regarding applications such as that submitted by Prof. Craker. Although DEA is required by law to publish a notice in the Federal Register "upon the filing" of an application for registration to manufacture a controlled substance,[24] DEA did not publish a notice until July 24, 2003, more than two years after Prof. Craker's initial application.[25] The required sixty-day comment period[26] ended on September 23, 2003, the only comment being an objection filed by Prof. Mahmoud El-Sohly, Director of NIDA's University of Mississippi cannabis farm. DEA is also required by law to approve or deny applications to manufacture a controlled substance and may not deny such an application without issuing an Order to Show Cause that gives the applicant an opportunity to request an administrative hearing to present evidence and argument as to why the application should be granted.[27] DEA has not taken any of these actions.

On July 21, 2004, Prof. Craker and MAPS sued DEA for unreasonable delay in responding to Prof. Craker's appli-

[23] Letter from Sens. Edward M. Kennedy and John F. Kerry, to Karen Tandy, Administrator, DEA (Oct. 20, 2003), *available at* http://www.maps.org/mmj/kkletter102003.html.

[24] 21 C.F.R. §1301.33(a).

[25] Manufacturer of Controlled Substances – Notice of Application. 68 Fed. Reg. 43, 755 (July 24, 2003).

[26] 21 C.F.R. §1301.33(a).

[27] 21 C.F.R. §§1301.33, 1301.35, 1301.37, 1301.41, and 1301.43.

cation. As of the date of this brief's filing, even a lawsuit has not resulted in any further action on Prof. Craker's application. DEA's failure even to deny Prof. Craker's application is an unjust and unreasonable obstruction to FDA-approved scientific research and is not a hallmark of a well-functioning approval process that would ensure the protection of patients' constitutional rights.

The government has used similar delay tactics in processing the application of Chemic Laboratories, Incorporated of Canton, Massachusetts (hereinafter "Chemic") to import cannabis for a MAPS-sponsored study to evaluate the contents of the vapor stream from a cannabis vaporizer.[28] This study does not involve human subjects nor require FDA approval but will provide valuable knowledge about alternative cannabis delivery systems that might spare patients exposure to the potentially harmful elements of cannabis smoke.

On June 24, 2003, Chemic submitted separate but related applications to the U.S. Department of Health and Human Services (HHS) and DEA seeking, respectively, approval of its research protocol so that Chemic could purchase 10 grams of cannabis from NIDA, and registration to import ten grams of cannabis from the Dutch Office of Medical Cannabis (the "DOMC"), part of the Dutch Ministry of Health. The DOMC operates in compliance with all international treaty obligations and is authorized to export cannabis to fully-licensed research projects. DOMC can supply cannabis of a quality that is unavailable from NIDA and is required to complete the later phase of the vaporizer study. DEA verbally advised

[28] MAPS and California NORML are sponsoring research into the use of vaporizer technology to heat the cannabis plant but not burn it. Preliminary evidence demonstrates that the vaporizer can release clinically significant amounts of cannabinoids without generating the compounds that come from combustion. This is part of an effort to develop non-smoking delivery systems for the cannabis plant.

Chemic that it would not process the application until HHS determines the scientific merit of the vaporizer protocol. DEA has also failed to publish a notice in the Federal Register, as is required by statute "upon the filing" of an import application, which is necessary to begin the 60-day comment period.[29]

HHS has failed to decide upon the scientific merit of the research protocol for over fifteen months. HHS's first communication to Chemic with respect to its application came on October 10, 2003, more than three months after it was submitted, stating that there was insufficient information in the application to judge the merits of the protocol. Although the application had complied fully with HHS's announced procedures, Chemic submitted an expanded and revised protocol on January 29, 2004. In the months after this submission, Chemic has made repeated attempts to ascertain the status of its application, which HHS officials have refused to divulge. On March 17, 2004, Rear Admiral, Assistant Surgeon General and Deputy Assistant Secretary for Health (Operations) Arthur J. Lawrence communicated via email that the application was awaiting only the HHS's required Public Health Service intermediate review process, but he could not say when that would occur.[30] He has subsequently ignored all further inquiries.

In contrast, pursuant to 21 C.F.R. § 1301.32(a), HHS review of applications and protocols submitted to it by DEA in the case of application for registration to conduct non-clinical research (such as Chemic's protocol), must be completed

[29] 21 C.F.R. §1301.34(a).

[30] Email exchange between Dr. Arthur J. Lawrence, Rear Admiral, Assistant Surgeon General and NIDA Deputy Assistant Secretary for Health (Operations), and Willem Scholten, Head of the Dutch Office of Medicinal Cannabis (Mar. 17, 2004), *available at* http://www.maps.org/mmj/vaporizer.html.

within 21 days after receipt of the application and complete protocol. In further contrast, FDA is required to review much more complicated protocols involving human subjects within 30 days.[31]

On June 9, 2004, MAPS received a letter from NIDA that is perhaps the most telling evidence of the futility of pursuing medical cannabis research under the current regulatory system. In this letter, NIDA Director Dr. Nora Volkow explained that

> As you know, NIDA is just one of the participants on the HHS review panel . . . It is not NIDA's role to set policy in this area . . . Moreover, it is not NIDA's mission to study the medicinal uses of marijuana or to advocate for the establishment of facilities to support this research. Therefore, I am sorry but I do not believe that we can be of help to you in resolving these concerns.[32]

These statements highlight the chilling effect that the NIDA monopoly has on research that could demonstrate how medical cannabis can be used to help sick Americans.

On July 14, 2004, MAPS and Valerie Corral[33] filed a lawsuit against both HHS and DEA alleging unreasonable delay in processing Craker's and Chemic's applications. Even after being sued, neither HHS nor DEA has offered any further information regarding the protocol and application.

Given such executive branch obstructionism, the UMass Amherst facility will likely require several years or more to become approved and operational, if it ever can. Attempts to

[31] *See* 21 C.F.R. § 312.20 (c).

[32] Letter from Dr. Nora Volkow, Director of NIDA, to Rick Doblin, President of MAPS (June 9, 2004), *available at* http://www.maps.org/mmj/mmjfacility.html.

[33] Valerie Corral is a California-licensed medical cannabis patient and caregiver and founder of the Wo/Men's Alliance for Medical Marijuana with an office at 230 Swanton Road, Davenport, California.

import cannabis for studies that would substantially contribute to the body of scientific knowledge regarding medical cannabis and its delivery have also been obstructed. For the foreseeable future, NIDA will continue to exert undue control over medical cannabis research as a result of its monopoly over the supply of cannabis, leaving suffering patients little recourse other than asserting their constitutional rights.

C. HHS's 1999 Guidelines Restrict Rather than Facilitate FDA-Approved Research.

In December 1999, HHS finally implemented a new written policy regarding the provision of cannabis to FDA-approved researchers, allegedly to expedite FDA-approved medical cannabis research.[34] However, rather than fulfilling its stated intent to facilitate research, HHS's new policy made research more difficult by adding yet another bureaucratic layer to the process.

HHS's guidelines require sponsors of privately funded and FDA-approved protocols who seek to purchase supplies from NIDA to submit their protocols for review and approval to the Public Health Service (PHS), an additional review process that exists exclusively for cannabis research.[35] HHS guidelines also specified a limited number of medical conditions for which cannabis should be tested, recommended that protocols be designed to prove cannabis equal or superior to existing medications despite FDA's statutory requirement to approve drugs if they are proven safe and efficacious as compared to placebo (since some patients may respond best to a medicine that is not on average equal to or better than

[34] Department of Health and Human Services, Guidance On Procedures for the Provision of Cannabis for Medical Research (1999), *available at* http://www.mpp.org/guidelines/hhsguide.html.

[35] The new HHS guidelines read, "After submission, the scientific merits of each protocol will be evaluated through a Public Health Service interdisciplinary process." *Id.*

other medicines), suggested that researchers conduct only "multi-patient" studies rather than "single-patient" studies which FDA also considers scientifically valid, and discouraged researchers from conducting studies with the goal of getting natural cannabis approved as a prescription medicine.[36] None of these restrictions apply to research with any other substance, even those in Schedule I. Especially problematic, the HHS guidelines establish no time limits within which HHS must evaluate protocols submitted to it for review.

Almost immediately, HHS's policy had a chilling effect on medical cannabis research. In September 1999, Dr. Ethan Russo received FDA approval for a protocol designed to examine the medical uses of cannabis in treatment-resistant migraine patients, an indication for which cannabis was utilized in mainstream Western medicine between 1842 and 1942.[37] In February 2000, NIDA refused to supply Dr. Russo with the necessary cannabis, based on criticisms of the protocol design by the PHS reviewers.[38] Since Dr. Russo's protocol was approved by FDA and would have been privately funded, the decision by PHS and NIDA not to provide the cannabis at cost effectively halted the standard FDA drug development process. As noted above, Chemic's HHS application also is currently stalled at the PHS stage, according to a NIDA official. Were it not for this additional

[36] *Id.*

[37] Letter from C. McCormick, Director of FDA Division of Anesthetics, Critical Care and Addiction Drug Products, to Dr. Ethan Russo (Sept. 21, 1999). *See also* Ethan Russo, *Cannabis for Migraine Treatment: The Once and Future Prescription?* 36 Pain, Jan.1998, at 3-8, *available at* http://www.druglibrary.org/crl/pain/Russo%2098%20Migraine_%20Pain.pdf.

[38] Letter from Steven W. Gust, Ph.D., Special Assistant to the Director of HHS, Public Health Service, to Dr. Ethan Russo (Feb. 1, 2000), *available at* http://www.maps.org/mmj/russo1199/02010001.html.

bureaucratic layer, HHS might have already issued a decision on the protocol's merits.

Clearly, these guidelines have not served to facilitate medical cannabis research. John Benson, M.D., principal investigator of the 1999 IOM report on medical cannabis, commented that "it's hard to discern that these guidelines have streamlined existing procedures."[39] For the foreseeable future, medical research with cannabis will proceed only as far and as fast as NIDA and HHS permit, regardless of the willingness of FDA to allow clinical trials to move forward.

D. HHS's Policy Makes it More Difficult to Research Cannabis Than Any Other Drug, Including All Other Schedule I Drugs.

Within the last ten years, FDA has approved several privately funded protocols involving the use of Schedule I substances such as MDMA (Ecstasy),[40] psilocybin,[41] and ibogaine. [42] Each of these studies has been or is being

[39] P. McMahan, *Oregon, Alaska Identify Legal Marijuana Users on State-Issued Cards*, USA Today, May 24, 1999, at A4.

[40] Approved November 5, 1992. Investigational New Drug (IND) #39,383. A Phase 1 dose- response safety study conducted by Dr. Charles Grob, Harbor UCLA. Approved November 2, 2001. IND #63,384, A Phase II pilot study conducted by Dr. Michael Mithoefer, Charleston, SC. The MDMA for both studies was manufactured under DEA license by Dr. David Nichols, Dept. of Medicinal Chemistry, Purdue University.

[41] IND # 56,530. Letter from C. McCormick, Director of FDA's Division of Anesthetics, Critical Care and Addiction Drug Products, to Dr. Francisco Moreno (Sept. 17, 1998). This protocol was approved but put on hold until a source of psilocybin could be arranged. MAPS arranged for Organix, Inc. of Woburn, MA to manufacture the psilocybin, with approval from DEA and FDA. This study is now in progress.

[42] On August 25, 1993, the FDA Drug Abuse Advisory Committee meeting recommended approving the Phase 1 dose- response safety study proposed by Dr. Juan Sanchez-Ramos and Deborah Mash, Ph.D.,

conducted with compounds obtained from private, non-governmental DEA-licensed manufacturers. The lack of an independent source of cannabis for use in FDA-approved clinical trials is an aberration and not the norm for Schedule I drugs.

E. Given the Difficulty of Conducting FDA-Approved Research, It is Unlikely that the FDA Will Be Able to Approve Cannabis as a Prescription Medicine in the Near Future, If Ever.

Despite high interest among doctors and medical researchers in developing cannabis for FDA-approved prescription use to treat serious illness, the federal government has placed so many obstacles in the way of that development that it is unlikely we will see any significant progress in the near future. The IOM, in a 1999 report commissioned by the White House Office of National Drug Control Policy to study the therapeutic uses of cannabis, noted that "it would likely be many years" before a safe and effective system of medical cannabis delivery would be available to patients.[43] IOM attributed the current lack of scientific study of medical cannabis to "a daunting thicket of regulations at the federal level" [44] and cited the "rigors of obtaining an adequate supply of legal, standardized marijuana for study"[45] as one of the challenges plaguing scientific research in this field. Nonetheless, HHS, DEA, and NIDA continue to obstruct research that would increase the body of knowledge about

University of Miami Medical School. The ibogaine for this study was imported by the researchers from Europe, with DEA approval.

[43] Institute of Medicine, Cannabis and Medicine: Assessing the Science Base, 7-8 (J. Joy, S. Watson, J. Benson, eds., 1999), *available at* http://stills.nap.edu/books/0309071550/html, pp. 7-8.

[44] *Id.* at 137.

[45] *Id.* at 217.

medical cannabis and its delivery, despite the fact that, as the IOM report notes, it is "widely used" by certain patient groups despite the uncertainty.[46]

Consequently, patients who are already medicating with cannabis under their doctors' supervision have little hope that the FDA drug-approval process will result in cannabis being made available as a prescription medicine. This pessimistic outlook has nothing to do with the actual therapeutic potential of cannabis and has everything to do with political obstacles that have subverted the FDA drug-approval process.

F. The Executive Branch Has Also Prevented Patients From Obtaining Relief by Participating in Single-Trial Studies, Contrary to the Recommendations of the Institute of Medicine.

The IOM suggested in its 1999 report that a possibility for helping patients currently suffering who might benefit from medical cannabis would be to allow them to participate in single-patient clinical trials, "in which patients are fully informed of their status as experimental subjects using a harmful drug delivery system, and in which their condition is closely monitored and documented under medical supervision." [47] IOM makes this recommendation in acknowledgment of the fact that there is "no clear alternative for people suffering from chronic conditions that might be relieved by smoking marijuana" and outlines several limiting conditions upon the population who would be eligible for participation in such studies.[48]

[46] *Id.* at 7.

[47] *Id.* at 7-8.

[48] *Id.*

However, HHS's policy as announced in its medical cannabis research guidelines, which formally took effect in December 1999, does not allow for this possibility despite IOM's recommendation. HHS's policy reads, in part:

> HHS intends to direct its program toward multi-patient clinical studies. As previously determined by [PHS], single-patient requests for marijuana raised a number of concerns including the fact that the single-patient IND process would not produce useful scientific information and we do not foresee that they would be supported under this program.[49]

Hence, the executive branch has not only shown its willingness to block congressional intent, but it has also disregarded the findings of the IOM of the National Academy of Sciences, chartered by Congress in 1863 to advise federal agencies. The result of this choice is that patients continue to suffer from debilitating conditions and must assert their constitutional rights to obtain relief.

II. BECAUSE THE FDA DRUG DEVELOPMENT PROCESS IS NOT WORKING AS CONGRESS INTENDED, PATIENTS WHO FOLLOW THEIR DOCTORS' ORDERS TO OBTAIN CANNABIS THROUGH ALTERNATIVE MEANS SHOULD BE PERMITTED TO ASSERT THEIR CONSTITUTIONAL RIGHTS TO USE CANNABIS

The Court should not rule against patients' constitutional rights to use cannabis based on the illusion of a well-functioning FDA-approval process. Pursuing legitimate, privately funded clinical research with cannabis is more burdensome than engaging in research with any other drug. As the Court considers the viability of patients' constitutional

[49] Department of Health and Human Services, Guidance On Procedures for the Provision of Cannabis for Medical Research (1999).

rights to use cannabis, it should consider that the lack of sufficient scientific data from FDA-approved controlled clinical trials to justify FDA-approval of cannabis as a prescription medicine is due in large part to the hindrance of research over the last several decades.

MAPS is a privately-funded research organization whose mission involves developing cannabis into an FDA-approved prescription medicine. Its mission has been sabotaged by its inability to obtain an independent source of supply of cannabis to use in its research. MAPS's offer to contract with NIDA's cannabis producer for supplies of cannabis that could be used in FDA-approved research was rejected, Prof. Craker's MAPS-sponsored application to DEA for a license to grow cannabis has not been responded to in over three years, and Chemic's MAPS-sponsored applications to DEA to import and to NIDA to purchase 10 grams of cannabis for further vaporizer research have not been responded to in over fifteen months. MAPS cannot contract, produce, import or purchase cannabis for its research efforts. As a result of these obstructions, MAPS has resorted to filing suit against DEA and HHS/NIH/NIDA, claiming unreasonable delay under the Administrative Procedures Act.

Thousands of seriously ill patients whose physicians consider their use of cannabis to be medically necessary for the treatment of their illnesses must risk criminal sanctions to obtain the relief they deserve. Many—if not all—of these patients would prefer to receive their medication through pharmacies. Short of that, many patients would appreciate the opportunity to participate in FDA-approved research as a means of gaining temporary, legal access to cannabis. Having been thwarted by bureaucratic obstacles impeding recourse through the FDA, medical cannabis patients currently have no practicable option but to assert their constitutional rights to use cannabis. Given the difficulties of conducting FDA-approved research into the medical uses of cannabis because

of past and continuing supply problems and HHS's unique and restrictive guidelines, it is unrealistic to expect that patients who have a legitimate medical need will be able to obtain legal access to cannabis via FDA-approved research in any substantial way at any point in the near future. Patients must therefore assert their constitutional rights to protect their lives and health from a governmental process that is not functioning as Congress intended.

CONCLUSION

For the foregoing reasons, Amici ask this Court to affirm the judgment of the court of appeals.

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October 13, 2004